REMARKS

Claims 1-18 were originally filed in the present application. New Claims 19 and 20 have been added by this Reply. Claims 1-20 are now at issue. Of the original claims, the Action of March 18, 2005, has rejected Claims 1-5, 9, 10 and 16 under 35 U.S.C. 102(b) as anticipated by Zaffaroni. Claims 1 and 4-6 stand rejected under 102(b) as anticipated by Jacobs. Claims 1-3, 9, 10 and 15 stand rejected under 102(b) as anticipated by Teran. Finally, Claims 7, 8, 11, 12 and 14 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs in view of Richie.

Applicant respectfully requests reconsideration of all rejections in light of the amendments to Claims 1, 3, 6, 10, 13, 16 and 18 and the arguments below. Applicant contends that all claims distinguish over the cited references and are in condition for allowance.

Current Amendments

Regarding independent Claims 1 and 16, the preamble of each now specifies that the device also enhances sexual stimulation. This amendment is supported by the specification at paragraphs 3, 5, 7 and 26, and in the Abstract. It is also now clear from Claims 1 and 16 that the second end of the device is inserted into the anal cavity of the same female into whose vaginal cavity the first end of the device has been inserted. This amendment is supported by the illustration of Figure 4 showing the device in use by a single female. Claims 1 and 16 have also been amended to provide that the device is configured for concurrent insertion into the anal cavity and the vaginal cavity. Finally, it is now clear that the ends and the intermediate portion of the device lie in the same plane and that the second end is inserted into the anal cavity after the first end is inserted into the vaginal cavity. Support for these amendments can be found in

paragraphs 25 and 26 of the application and Figure 4. No new matter has been added by any of these amendments.

Claims 1, 3, 6, 10, 13 and 16, the specification, and the Abstract have been amended to replace the term "S-shaped" with "curved." This amendment has been made voluntarily to more accurately describe the device as depicted in Figures 1-4. Paragraphs 8 and 9 of the specification have been amended to conform to the language of the amended claims. No new matter has been added by these amendments.

Claim 18 has been amended to depend from independent method Claim 17. No new matter has been added by this amendment.

Section 102(b) Rejections

In order for a reference to act as a §102 bar to patentability, the reference must teach each and every element of the claimed invention. Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 771 (Fed. Cir. 1983). Without the required teaching of "each and every element" as set forth in the claims, it is improper for the Examiner to continue such rejections under §102(b).

U.S. Patent No. 3,971,367 to Zaffaroni (the '367 patent) is directed to an intrauterine device used for drug delivery. Applicant respectfully contends that none of Claims 1-5, 9, 10, and 16 are anticipated by the '367 patent because it lacks disclosure of each and every element. The amended claims now indicate that the intermediate portion and the ends of the device lie in the same plane. This is clearly a structural feature of the device which distinguishes over the '367 patent. There is no indication from Figure 6 or in the description of the '367 patent that the ends and the intermediate portion of the disclosed device lie in the same plane. Accordingly, the

'367 patent cannot be said to anticipate the invention of Claims 1-5, 9, 10 and 16. Reconsideration and withdrawal of this rejection is requested.

Further, Applicant contends the language of the claims is not purely functional as suggested by the examiner, and should therefore be given patentable weight. The phrase "such that the second rounded end may be inserted into the anal cavity once the first rounded end has been inserted into the vaginal cavity" is not purely functional in nature. This phrase refers to a limitation directed to the structural configuration of the curved intermediate portion of the device and sets definite parameters for the limitation. That is, the device is not merely curved, but it is curved in a manner such that the ends can be properly inserted into the two distinct female cavities. The examiner's refusal to give weight to the language solely because it is considered functional is improper.

First, a functional limitations must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the art. See MPEP 2173.05(g). Accordingly, the examiner is not permitted to unilaterally discount a limitation merely because she considers it to be functional. Second, when considered, the functional language meets the requirements of 35 U.S.C. 112, second paragraph, if it sets definite boundaries on the claimed invention. For example, the functional language "incapable of forming a dye with said oxidizing developing agent" used to define a radical on a chemical compound, though completely functional, was found to be perfectly acceptable because it set definite boundaries on the patent protection sought. In re Barr, 444 F.2d 588, 170 U.S.P.Q. 33 (CCPA 1971).

With regard to the language of Claims 1 and 16, those skilled in the art would understand the female anatomy and could determine the desired curvature needed to meet the claim requirements. A device configured with curves which could not be so inserted, does not read on and, therefore, does not anticipate the claim.

Referring to Figure 6 of the '367 patent, it is clear that, though curved, the disclosed device is not capable of concurrent insertion of one end into the vaginal cavity and the other end into the anal cavity of a female. Accordingly, the '367 patent does not meet the "each and every element" requirement of a proper 102 reference against Claims 1 and 16. Applicant respectfully requests reconsideration and withdrawal of this rejection.

Claims 2-5 and 9-10 are either directly or ultimately dependent on Claim 1 and thus should also be considered to distinguish over the cited '367 patent.

U.S. Patent No. 5,863,362 to Jacobs (the '362 patent) is directed to a glandular stimulator. The '362 patent does not disclose a device for simultaneous insertion into the user's anal and vaginal cavity. The size and structure of each of the embodiments of the device disclosed in the '362 patent as depicted in Figures 5, 6, 11, 16, 18, 20, 21 and 23 demonstrate that the ends of those devices are not capable of concurrent insertion into the same female's vaginal cavity and anal cavity. Many of those figures depict multiple users. Furthermore, the '362 patent discloses that the device must be "of sufficient rigidity to resist bending." Therefore, it cannot be said that the disclosed device could be bent to enter the same females anal and vaginal cavities. The ends of the device of the '362 patent are thus not spaced from each other for concurrent insertion as set forth in Claim 1 of the present application.

Further, the configurations of the device disclosed in the '362 patent do not cradle the Kegel muscle, thus allowing the first end to remain inserted within the vaginal cavity when the second end has been inserted into the anal cavity. The fulcrum of the '362 patent would not bear against the front wall and the back wall of the user's Kegel muscle, as set forth in Claim 1.

Accordingly, the '362 patent fails to disclose each and every element of the invention. Reconsideration and withdrawal of the rejection in light of the amendments is respectfully requested. As Claims 4-6 depend directly from Claim 1, rejection of these claims should also be withdrawn.

U.S. Application Publication No. 2003/0104909 to Teran (the '909 application) has been cited against Claims 1-3, 9, 10 and 15. Applicant respectfully traverses this rejection and requests reconsideration.

Claim 1, as amended, clearly states that the intermediate portion and the end portions of the device lie in the same plane. Figures 1 and 9 in the '909 application clearly demonstrate that the intermediate portion and the ends of the disclosed device do not lie in a single plane.

Further, as argued above, the language discounted by the examiner as functional dictates definite structure to one of skill in the art. The ends and intermediate portion of the device disclosed in the '909 application are clearly not structured or spaced to permit concurrent insertion of the first end into a female's vaginal cavity and the second end into the same female's anal cavity.

The examiner states that if the cited device is capable of performing the intended use, then it meets the claim. According to paragraph 21 of the '909 application, hook portion 20 of the disclosed device is sized so that a user may grasp hook portion 20 with his or her hand. Such

sizing would make it impossible to insert the end of the disclosed device into a female's anal cavity when the first end is in the same female's vaginal cavity. Furthermore, the '909 application device is not configured for such insertion. The intermediate portion of the device would abut against the user's Kegel muscle, rendering such insertion impossible. Accordingly, the '909 application fails to meet the "each and every limitation" requirement for a proper 102 rejection and should therefore be withdrawn as to Claim 1.

Claims 2, 3, 9, 10 and 15 are directly or ultimately dependent upon Claim 1, merely adding additional elements to the base claim, and should be considered to distinguish over the '909 application as well. Reconsideration is respectfully requested.

Section 103(a) Rejections

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicants' disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Claims 7, 8, 11, 12 and 14 have been rejected under 103(a) as unpatentable over Jacobs in view of U.S. Patent Application Publication No. 2003/0097041 to Ritchie et al (the '041 application). Neither the '362 patent nor the '041 application discloses a device configured to permit concurrent insertion of the device in the same female's vaginal cavity and anal cavity.

Furthermore, the subject matter of these references combined would not allow for concurrent insertion. In fact, the device disclosed by the '041 application is intended to be used by males not females, as evidenced by the use of penile loop 32 which encircles the user's penis (page 2, paragraph 32). A person of ordinary skill in the art would not even apply the teaching of the '041 application to the '362 patent. The Office Action points to no teaching or suggestion within the '362 patent or the '041 application which would lead one skilled in the art to combine these devices. Applicant respectfully traverses this rejection and requests reconsideration in light of the above-amendments.

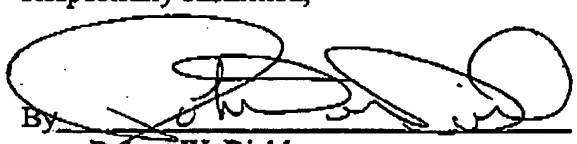
Finally, the examiner states that the evidence of record does not teach the criticality of the dimensions of the spheres of the applicant's device or the length of the applicant's device. Regarding the length of the claimed device, paragraph 25 of the present application clearly explains that the length of the device permits the user to insert the second sphere into the anal cavity comfortably when the first sphere is in the vaginal cavity. As for the dimensions of the spheres, the examiner is referred to paragraph 26 where it is explained that the first sphere is sized such that it may localize pressure upon the Graphenburg spot and the second sphere is sized to permit the user to manipulate the device by drawing the second sphere further into the anal cavity by contracting the sphincter muscle. It is therefore submitted that the application clearly teaches the criticality of the dimensions of the spheres and the length of the device. None of the cited references, taken either alone or in combination, disclose spheres at the ends of the device and thus do not disclose relative or actual sizes of those spheres.

CONCLUSION

Claims 1-20 are currently pending in the present application. Claims 19 and 20 have been added by this Reply, while Claims 1, 6, 10, 13, 16 and 18 have been amended. All claims are considered to distinguish over the cited references. Accordingly, Applicant requests reconsideration and withdrawal of all rejections and notice of allowance of all claims at the examiner's earliest convenience.

Should any informalities remain which can be addressed by Examiner's Amendment, the examiner is requested to call the undersigned in order to expedite prosecution of the present case.

Respectfully submitted,



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